EXHIBIT 19

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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ANNIE TUMMINO, et al.,

Plaintiffs,

v.

DECISION AND ORDER

ANDREW C. VON ESCHENBACH, in his official capacity as Commissioner of the Food and Drug Administration,

Defendant.

CV 05-366 (ERK)(VVP)

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POHORELSKY, Magistrate Judge:

Before the court are various issues concerning discovery in this action, which challenges several determinations made by the Food and Drug Administration ("FDA")[1] concerning Plan B, the so-called "morning after" pill. The plaintiffs seek an order requiring the production of various documents withheld on the basis of the deliberative process privilege, and have identified various items of discovery they wish to complete. The defendant seeks a protective order quashing all present and future discovery in this matter, and in the alternative an order prohibiting discovery from the White House. Much of the factual and procedural background for these issues has been addressed in other opinions of the court, familiarity with which is presumed. For the reasons below, the motion for a protective order is denied, and discovery shall proceed as set forth in the following rulings.

I. THE DEFENDANT'S MOTION FOR A PROTECTIVE ORDER

As the protective order sought by the defendant would preclude the need to address the other discovery issues, the court addresses that motion first. The FDA had sought a similar protective order precluding all discovery and limiting this court's review to the administrative

[1]Because the individual defendant is sued in name only, the real party in interest is the defendant here is the FDA, and this opinion accordingly refers to the FDA as if it were the defendant.

record earlier in the proceedings. That motion relied primarily on the so-called "record rule," which generally limits judicial review of agency decisions to the administrative record identified by the agency. The court denied the motion in a February 2006 decision on the basis of various exceptions which, if established, would allow "extra-record investigation by the reviewing court . . . ." *Tummino v. von Eschenbach*, 427 F. Supp. 2d 212, 230 (E.D.N.Y. 2006) (quoting *Nat'l Audubon Soc'y v. Hoffman*, 132 F.3d 7, 14 (2d Cir. 1997)) (additional citations omitted). Those exceptions included, "[1] a strong showing in support of a claim of bad faith or improper behavior on the part of agency decisionmakers or [2] the absence of formal administrative findings [which] makes such investigation necessary in order to determine the reasons for the agency's choice." *Id.* (quoting *Hoffman*, 132 F.3d at 14 (citations omitted)). This court also recognized, as an additional basis for piercing the administrative record, that the plaintiffs' claims included one which sought to "compel agency action unlawfully withheld or unreasonably delayed." *Id.* at 231 (citing *Friends of the Clearwater v. Dombeck*, 222 F.3d 552, 560 (9th Cir. 2000)) (additional citations omitted). In denying the FDA's motion for a protective order, the court concluded that the plaintiffs had made a sufficiently strong showing of bad faith on the part of FDA officials to warrant discovery beyond the administrative record. *See id.* at 231-34.

The instant motion rests on recent decisions by the FDA which constitute final agency actions on the two applications that underlie the plaintiffs' claims. Specifically, the FDA has denied the Citizen's Petition seeking approval of over-the-counter ("OTC") sales of Plan B without age restrictions and has granted an amended supplemental new drug application

("SNDA") which permits Barr Laboratories to make OTC sales of Plan B to persons 18 and older.

The defendant argues that these agency actions render the plaintiffs' unreasonable delay claim moot, an argument that the plaintiffs cannot, and do not, contest. Indeed, the plaintiffs have withdrawn the unreasonable delay claim in a recently filed amended complaint, but continue to assert two other claims under the Administrative Procedure Act ("APA"). Specifically, the fifth amended complaint attacks the decisions imposing age restrictions on OTC access to Plan B as "arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law," in violation of 5 U.S.C. § 706(2)(a), and as beyond its statutory authority, in violation of 5 U.S.C. § 706(2)(c). Thus, the withdrawal of the unreasonable delay does not end the court's inquiry into the FDA's decisionmaking processes. And extra-record review of agency decision-making is just as appropriate when the claims involve final agency action as when the claims involve claims of unreasonable delay. *See, e.g., Sokaogon Chippewa Cmty. v. Babbitt*, 961 F. Supp. 1276 (W.D. Wis. 1997). Thus, the mere change of claims does not render moot the court's previous finding that a preliminary showing of bad faith justifies discovery beyond the administrative record.

The defendant takes the argument one step further, however, by arguing that because the unreasonable delay claim is moot, the agency's delays in making its decisions are immaterial and cannot amount to bad faith justifying judicial review beyond the administrative record. The argument is flawed for at least two reasons. First, it rests on the faulty premise that the FDA's delays were the principal basis for the court's conclusion that a strong preliminary showing of bad faith had been made. A review of the court's decision discloses that delay was but one of

the factors considered by the court in reaching that determination. The other factors included questionable conduct surrounding various interim determinations made by the FDA in addressing Plan B issues. The FDA seeks to deflect the significance of that conduct by arguing that the FDA's interlocutory decisions are not reviewable by this court, a premise that, itself, is of dubious merit. *See* 5 U.S.C. § 704 ("A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action."). It can only follow then that the court be able to consider the agency's conduct surrounding those interlocutory decisions in reaching a determination that a strong preliminary showing of bad faith remains. And this is true regardless of whether the plaintiffs here have standing to challenge the final decision concerning Barr's SNDA for, as the defendant's counsel acknowledges, the agency's actions on the Citizen's Petition and Barr's SNDA were intertwined. See July 26, 2006 Tr. at 40:16-19 ("if Barr wins, they win, and if Barr loses, they lose").[2]

Second, and perhaps more importantly, the FDA's delays in making its determinations continue to be relevant to a showing of bad faith even though final decisions have been made. Unreasonable delay itself can, of course, constitute arbitrary and capricious conduct. *See Coit Independence Joint Venture v. Federal Sav. and Loan Ins. Corp.*, 489 U.S. 561, 590 (1989) (Scalia, J., concurring in part). Although unreasonable delay by itself furnishes no basis for relief once final agency action is taken, it does not lose its relevance as a factor to be considered in determining whether it is appropriate to extend review of that final agency action beyond the administrative record. In other words, if questionable delay, coupled with other factors, is found

[2]The term "Tr." preceded by a date refers to the transcript of a conference or hearing held on the date indicated.

to establish a strong preliminary showing of bad faith justifying review beyond the administrative record, that strong preliminary showing does not evaporate simply because the agency finally took action that had been unreasonably delayed.

The court thus finds no basis for upsetting its prior determination that the plaintiffs have made a sufficiently strong preliminary showing of bad faith that justifies discovery beyond the administrative record. Accordingly, the motion for a protective order staying the completion of discovery is denied.

II. DISCOVERY TO BE COMPLETED

The plaintiffs have identified essentially three areas of discovery that remain to be pursued. First, they wish to depose Dr. Sandra Kweder, an FDA employee, concerning her knowledge of matters relating to decisions made by the FDA. Second, they wish to serve subpoenas for documents from the White House and testimony from a former member of the White House staff, Jay Lefkowitz, concerning contacts between the White House and high-ranking officials of the FDA about Plan B. Finally, they wish to complete outstanding documentary discovery which includes the court's review of documents withheld by the defendant on the basis of the deliberative process privilege.

A. Deposition of Dr. Kweder

As the defendant does not oppose the deposition of Dr. Kweder on any grounds other than that all discovery should be stayed (although he contends her testimony would be cumulative), the plaintiffs should schedule and complete her deposition as soon as reasonably convenient.

B. Subpoenas for White House Information

The defendant's opposition to discovery from the White House rests largely on separation of powers concerns, as enunciated in *Cheney v. United States District Court*, 542 U.S. 367 (2004), which arise when the vice-president and other senior officials in the executive branch are directed to provide discovery. The defendant's standing to raise those concerns is suspect, since the defendant is not asserting his own interests but the interests of absent third parties. Thus, parties typically are deemed to lack standing to quash subpoenas issued to non-parties under Rule 45 absent a claim of privilege or some proprietary or personal interest in the subpoenaed matter. *See, e.g., Estate of Ungar v. Palestinian Authority*, 400 F. Supp. 2d 541, 554 (S.D.N.Y. 2005); *Auto-Owners Ins. Co. v. Southeast Floating Docks, Inc.*, 231 F.R.D. 426, 429 (M.D. Fla. 2005); *Washington v. Thurgood Marshall Academy*, 230 F.R.D. 18, 21 (D.D.C. 2005); *Green v. Sauder Mouldings, Inc.*, 223 F.R.D. 304, 306 (E.D. Va. 2004). A party may of course seek a protective order under Rule 26(c), even as to discovery sought from third parties, but in those circumstances the party generally must be seeking to protect its own interests in precluding the discovery, not the interests of the third party. *American Rock Salt Co., LLC v. Norfolk Southern Corp.*, 228 F.R.D. 426, 466 (W.D.N.Y. 2004); *see also* 8 Charles Alan Wright, Arthur R. Miller & Richard L. Marcus, *Federal Practice And Procedure* § 2035, at 475 (2d ed. 1994) ("A party may not ask for an order to protect the rights of another party or a witness if that party or witness does not claim protection for himself, but a party may seek an order if it believes its own interest is jeopardized by discovery sought from a third person.").

The court is particularly reluctant to consider the separation of powers concerns raised by the defendant now that his counsel has reversed their initial position that the government would

abide by whatever rulings this court made concerning the discovery sought by the plaintiffs from the White House. (*Compare* Oct. 11, 2006 Tr. 44:17-45:17, *with* Aug. 3, 2006 Tr. 23:16-24:4.) As the White House and the members of its staff from whom the information is sought are not before this court, in the absence of their agreement to abide by this court's decision any ruling made here on those issues would be simply advisory. Rather, because any subpoena for the information sought by the plaintiffs from the White House must emanate from the United States District Court for the District of Columbia, the White House and its staff have the right to have any separation of powers issues, which they will undoubtedly raise, determined by that court. *See* Fed. R. Civ. P. 45(c).

Although this court therefore declines to rule on the separation of powers arguments, as relevancy is part of the *Cheney* calculus in resolving separation of powers concerns, this court offers the following brief observation about the relevancy of the information sought from the White House. The central theory of the plaintiffs' claims here is that the FDA's decisions concerning Plan B were arbitrary and capricious and contrary to law because they were guided by improper political considerations. There is no dispute that high officials of the FDA, including two commissioners, had direct discussions with members of the White House staff concerning the FDA's decisions about Plan B. (*See* Oct. 11, 2006 Tr. 25:2-8.)[3] Information concerning the content of those communications is thus directly relevant to the question whether improper political considerations infected the commissioners', and therefore the FDA's, decisionmaking processes. In deposition testimony, the commissioners themselves have

[3]Jay Lefkowitz, the individual whom the plaintiffs wish to depose, is described by the defendant as "a former high-ranking advisor to the President." (Def.'s Mem. Supp. Prot. Order Mot. 1.)

characterized the discussions as purely informational. But that should not prevent to the plaintiffs from testing those characterizations by obtaining discovery from the other participants in those discussions by means of sufficiently specific document requests and depositions. The court has not closely examined the proposed scope of discovery sought from the White House by the plaintiffs. The question of how broad the discovery ought to be is best left to the court that hears from the persons subpoenaed concerning the burdens the requests impose on them, and the separation of powers concerns that the requested discovery raises. It is enough for this court to say that some measure of inquiry into White House involvement in Plan B decisionmaking ought to be allowed.

C. Documents Withheld Under Deliberative Process Privilege

Some background is necessary before proceeding to the merits of the parties' arguments concerning the documents withheld by the defendant on the basis of the deliberative process privilege. At a discovery hearing on May 31, 2006, this court overruled the defendant's assertion of the deliberative process privilege as a basis for withholding documents sought by the plaintiffs in their second set of document requests.[4] The defendant appealed that ruling[5] to Judge

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[4]That request seeks the production of "all correspondence, including email correspondence, concerning Plan B that was received by, sent by, or copied to any of the following individuals: Jane Axelrad, Jin Chen, Lester Crawford, Steven Galson, John Jenkins, Mark McClellan, and Janet Woodcock." (Pls.' Letter to Mag. J. Pohorelsky, May 5, 2006, *available at* docket. entry 133.)

[5]The following colloquy took place at the hearing, which forms the basis of the defendant's objection:

> MR. AMANAT: [Y]our Honor, just to clarify for the record your Honor's ruling with regard to deliberative process privilege. Am I correct in understanding that your Honor has precluded the government from asserting the deliberative process privilege in regards to any document that may be responsive to these discovery requests?
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> THE COURT: No, you can assert any privilege you want but the deliberative process privilege

Korman, who deferred decision on the objection, opting instead to deal with the issue "on a practical basis." (July 26, 2006 Tr. 4:3-4.) To that end, Judge Korman provided the defendant an opportunity (without prejudice to any arguments advanced by the plaintiffs) to withhold, and subsequently submit to this court for *in camera* review, a subset of the assertedly privileged documents. In conducting the *in camera* review, this court was instructed to "consider whether the documents evidence bad faith such that they would be directly relevant to the plaintiff's claims and assure that the privilege [sic] documents are not merely duplicative of previously-disclosed documents." (Minute Entry and Order for July 26, 2006 Status Conference, *available at* docket entry 179.) Judge Korman instructed further that those documents which this court finds evidence bad faith should be disclosed by the defendant. (*See* July 26, 2006 Tr. 13 ("[T]he instruction to the magistrate should be is that if in his judgment it is deliberative, these documents evidence bad faith, that they should be disclosed.").) In accordance with Judge Korman's directions, the defendant submitted 1,179 pages of documents along with a privilege log and supporting affidavit by an FDA official to this court for *in camera* review. (*See* Def.'s Letter to Mag. J. Pohorelsky, Aug. 11, 2006, *available at* docket entry 183.) In the defendant's estimate, this submission constitutes approximately fifteen to twenty percent of the assertedly privileged documents responsive to the document request at issue. (July 26, 2006 Tr. 4:19-24.) More significantly, as counsel for the defendant pointed out at the latest hearing, this 1,179-page

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> is not a basis to withhold production. I am overruling that as a basis on which to withhold production. It's a qualified privilege and the privilege in my view with respect to deliberations concerning Plan B has been effectively taken out of this case by the Court's prior [February 2006] ruling.

(May 31, 2006 Tr. 62:12-63:5.)

submission represents only "one-sixth" of the documents the defendant intends to withhold on the basis of the deliberative process privilege. (Oct. 11, 2006 Tr. 42:11-22.)

The plaintiffs have challenged the defendant's *in camera* submission, arguing that the log itself is insufficient in some respects and questioning the assertions of the privilege as to some of the documents identified in the log. (*See* Pls.' Letter to Mag. J. Pohorelsky 1-4, Aug. 29, 2006, *available at* docket entry 191.) The plaintiffs also point to various documents identified in the log which, in their view, are likely to evidence bad faith. (*See* Pls.' Response to Def.'s Aug. 11, 2006 Privilege Log, *available at* docket entry 191.)

Given the parties' positions and Judge Korman's instruction, the court's task here is threefold. First, the court must make a threshold determination as to whether the privilege applies at all to the documents withheld by the defendant. Certainly, those documents found to be non-privileged must be disclosed. Indeed, the defendant construes the plaintiffs' opposition to its *in camera* submission as a "motion to compel production of documents withheld on the basis of the deliberative process privilege." (*See, e.g.*, Def.'s Mem. of Law Opp'n Pls.' Mot. to Compel, *available at* docket entry 202.) These non-privileged document are listed in Appendix A. Second, the court must undertake the task assigned by Judge Korman, namely, reviewing the remaining documents, i.e., those not listed in Appendix A, for evidence of bad faith, and ordering the disclosure of those that contain such evidence. Those documents that evidence bad faith are identified in Appendix B. As to the remainder of the submission, i.e., documents not listed in Appendices A and B, including the accompanying privilege log, the court addresses various defects it finds with the defendant's assertion of the privilege. Those documents which exhibit such defects are listed in Appendix C.